UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC.,

Plaintiffs and Counter-Defendants,

-against- No. 17 Civ. 9922 (CM)

SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, AVADEL SPECIALTY PHARMACEUTICALS, LLC,

Defendants and Counterclaimants.

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DECISION ON MOTIONS *IN LIMINE*

McMahon, C.J.:

The court, for its decision on Counterclaimants' and Ferring's motions *in limine*:

Counterclaimants' *In Limine* Challenges

Counterclaimants have filed three *in limine* motions that seek to (i) preclude Ferring's indefiniteness theory (Dkt. No. 646); (ii) exclude testimony and argument related to Ferring's failed claim construction positions (Dkt. No. 649); and (iii) to preclude Ferring from offering evidence or argument related to Dr. Fein's response to the Notice of Opposition in the European Patent Office ("EPO") proceeding. (Dkt. No. 651.)

Each will be considered in turn.

A. Motion to Preclude Ferring's Indefiniteness Theory

1. Background

Ferring's pretrial submission (Dkt. No. 637, Ex. 2) indicates that it intends to present argument or evidence at trial in support of the theory that certain asserted claims of the patents-in-suit are invalid based on indefiniteness. (35 U.S.C. § 112 ¶ 2.) Specifically, Ferring intends to present a defense at trial that the "about" limitations of several asserted claims are indefinite (e.g., '321 patent, cl. 6 ("wherein the method produces a plasma/serum desmopressin concentration in the patent of a maximum of no more than **about** 10 pg/ml")).

Counterclaimants allege that the indefiniteness theory was "undisclosed" because while Ferring asserted an indefiniteness claim in its original Complaint for Declaratory Judgment (1) neither that pleading, nor Ferring's Amended Complaint for Declaratory Judgement, contain allegations related to the "about" claim limitations, (2) Ferring's Answer to Counterclaimants' infringement counterclaim did not plead that the "about" claim limitations are indefinite (Dkt. No. 18 ¶¶ 132-137; Dkt. No. 22 ¶¶ 132-137), (3) neither Ferring's initial nor final invalidity contentions disclosed an invalidity theory based on indefiniteness.

After the close of fact and expert discovery, Ferring asked to depose Counterclaimants' expert, Dr. Mayersohn, on his rebuttal report related to Ferring's enablement defense. According to Counterclaimants, it was then that Ferring asked Dr. Mayersohn questions relating to the "about" claim limitations. The basis of Ferring's indefiniteness theory arise out of Dr. Mayersohn's response to Ferring's questions related to indefiniteness. (Dkt. No. 637, Ex. 2 at 64, DFF249-250). Ferring is not relying on its own expert testimony to establish the indefiniteness theory, but rather, on the testimony of Counterclaimants' expert.

Counterclaimants allege that they reasonably relied on the fact that Ferring had abandoned its original indefiniteness defense (which were not directed at the "about" claim limitations), because Ferring did not include any indefiniteness theories in its initial or final invalidity contentions. Therefore, Counterclaimants sought no discovery on indefiniteness and did not develop or disclose expert testimony on the issue.

2. Counterclaimants motion to preclude Ferring's indefiniteness theory is GRANTED

Ferring's failure to disclose its indefiniteness theory in both the initial and final invalidity contentions precludes it from asserting its "about" limitation indefiniteness theory because it would unduly prejudice Counterclaimants.

Courts have granted motions *in limine* to preclude untimely disclosed theories. For example, in *Abbot Labs. v. Sandoz, Inc.*, 743 F. Supp. 2d 762, 777 (N.D. Ill. 2010), the defendant did not disclose its enablement and written description defense theories in any expert report, nor in defendant's initial or final invalidity contentions. *Id.* at 774-75. The court found that the important inquiry in resolving plaintiff's *in limine* motion was whether plaintiff had sufficient notice of its intended defense during discovery such that it would not be prejudiced by introduction at trial. *Id.* at 776. The defendant argued that plaintiff's expert's construction of certain claim terms, along with defendant's expert's analysis of those constructions, implied the foundation for the new defense theories. *Id.* The court rejected the argument because this supposed notice by the defendant was "too subtle to compensate for its failure to disclose these defenses during discovery" and granted plaintiff's motion *in limine* to preclude argument or evidence at trial of defendant's new and untimely disclosed theories of invalidity. *Id.* at 777.

Here, Ferring argues that its disclosure of its indefiniteness defense is timely because it notified Counterclaimants of its indefiniteness defense by serving Supplemental and Amended Invalidity Contentions on December 6, 2019 ("Supplemental Contentions"), within a month of Dr. Mayersohn's final deposition and a few months before trial. According to Ferring, at Dr.

Mayersohn's November 2019 deposition, he sought to "roll back the opinions in his Second Rebuttal Report … and, in doing so, indicated that he could not determine the scope of the claims—creating an indefiniteness argument." (Dkt. No. 661 at 3.) Ferring says that it raised this indefiniteness defense "shortly after it became clear that a person of ordinary skill (i.e., Dr. Mayersohn) could not determine the actual scope of the asserted claims." (*Id.*)

Ferring's argument is unavailing. Counterclaimants' expert rebuttal report could not "create" an indefiniteness argument, as Ferring claims. Indefiniteness, like the reasonable person standard, is an objective standard.[1] *See Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*) (noting that "the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art"). The subjective ability of Counterclaimants' expert to determine the scope of the asserted claims does not give rise to an indefiniteness claim.

If the asserted claims with the "about" limitations were indefinite during Counterclaimants' expert testimony, they were indefinite when Ferring filed its initial and final invalidity contentions. Ferring has known about the patents-in-suit – including the asserted claims with the "about" limitations – since at least 2012 when it filed the 2012 Action. It might have *occurred* to Ferring that it could raise such an argument during the deposition, but this is a far cry from stating that the expert's opinion "created" the defense.

Permitting such argument or testimony at trial would frustrate the disclosure requirements of the Federal Rules and unduly prejudice Counterclaimants, who had no notice of this theory during fact or expert discovery and had no opportunity to conduct discovery into or elicit expert witness opinions in response.

B. Motion to Exclude Testimony and Argument Related to Ferring's Failed Claim Construction Positions

1. Background

On January 22, 2019, Judge Sweet handed down the claim construction order for this case. (Dkt. No. 421.) The Court issued, *inter alia*, the following constructions:

- "**Transmucosal**" ('203 patent, cls. 6, 10, 13; '321 patent, cls. 1, 12): "delivering desmopressin by way of mucosal tissue, such as the sublingual mucosa"
- "**Transmucosal delivery/transmucosal … delivery**" ('203 patent, cls. 6, 10, 13): "delivering desmopressin by way of mucosal tissue, such as the sublingual mucosa"
- "**Delivering to the bloodstream … by [via] transmucosal… administration**" ('321 patent, cl. 1): administering desmopressin by way of a mucosal tissue, such as the sublingual mucosa

[1] "A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). Further, "terms of degree such as 'substantially,' 'about,' or 'closely approximate' do not necessarily render the claim indefinite, so long as the term 'provide[s] enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014).

- "**Transmucosal administration/administering … by transmucosal administration**" ('203 patent, cl. 12)" administering desmopressin by way of a mucosal tissue, such as the sublingual mucosa

(Dkt. No. 421.) Essentially, Judge Sweet held that transmucosal *administration/delivery* of desmopressin does not require transmucosal *absorption* of desmopressin. In so doing, he rejected Ferring's proposal that transmucosal administration, which is required by certain asserted claims, necessitates transmucosal absorption.

In Ferring's Proposed Findings of Fact and Conclusions of Law and direct witness statements, Ferring has disclosed that it plans to solicit testimony from Dr. Fein along the following lines: "Dr. Fein has admitted his invention requires sublingual absorption, but the patents in suit do not claim sublingual absorption. [Anticipated testimony of Dr. Fein]" (Dkt. No. 637, Ex. 2 at DFF259.)

2. Counterclaimants' motion to exclude testimony and argument related to Ferring's failed claim construction positions is DENIED

Counterclaimants aver that "Because the claims have already been construed by the Court and Dr. Fein's understanding of his own invention is irrelevant to the determination of proper inventorship or patent validity, Ferring's related evidence and arguments have no probative value" (Dkt. No. 650 at 3) and that its probative value is therefore substantially outweighed by confusion of issues, unfair prejudice to Counterclaimants, and waste of time.

Counterclaimants motion is deficient primarily because Counterclaimants mischaracterize Ferring's intentions regarding claim construction. Ferring does not seek to "reargue" claim construction. Counterclaimants have affirmatively put Dr. Fein's invention story and his understanding of his invention at issue by submitting a direct witness affidavit from Dr. Fein that includes a section testifying about his purported "Desmopressin Inventions." (Dkt. No. 623 at ¶¶ 31-35.) In the affidavit, Dr. Fein explains that his invention is predicated on sublingual absorption:

> So, I said this new dosage form, the orodispersible tablet, provides an opportunity to avoid the oral route of administration if it were adapted to be placed under the tongue. That's called sublingual route of administration, and what it means is that the drug is dissolving and being directly absorbed into the bloodstream through the capillary bed under the tongue. That's a type of transmucosal route of administration or transmucosal absorption.

(Dkt. No. 623 at ¶¶ 34-35.) Ferring intends to make the point that with respect to the patents in suit, Dr. Fein did not claim sublingual absorption and therefore his purported contributions are limited to low dose and sublingual administration. The fact that the construed claims do not require Dr. Fein's purported contribution of sublingual absorption is relevant to the determination of whether Dr. Fein invented what is claimed.

With respect to 102(f), an inventorship analysis "begins as a first step with a construction of each asserted claim to determine the subject matter encompassed thereby. The second step is

then to compare the alleged contributions of each asserted co-inventor with the subject matter of the properly construed claim to then determine whether the correct inventors were named." *Trovan, Ltd. v. Sokymat SA, Irori*, 299 F.3d 1292, 1302 (Fed. Cir. 2002).

The first step of the analysis was completed by the Court in its claim construction analysis. As to the second step, courts look to both the alleged inventor's purported contributions to the construed claims (i.e. Ferring's contributions) as well as the purported contributions of the named inventor to those claims (i.e., Fein's contributions). *See Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, No. 98-cv-7766, 2007 WL 1552395, at *5-6 (S.D.N.Y. May 29, 2007) (comparing evidence of named inventor's versus the alleged inventor's contributions to the claims in § 102(f) analysis); *Finkelstein v. Mardkha*, 495 F. Supp. 2d 329, 340 (S.D.N.Y. 2007) (same). The fact that the construed claims do not require Dr. Fein's purported contribution of sublingual absorption is relevant to the determination of whether Dr. Fein invented what is claimed. It is also relevant to Ferring's § 112 arguments, including the written description requirement which ensures that the "inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351.

At its core, what Counterclaimants ultimately seek is an order precluding Ferring from cross-examining Dr. Fein on his direct witness affidavit and how his "invention story" detailed therein relates to the invention claimed in the patents in suit. However, this cross-examination is relevant to claims and defenses Ferring has raised including invalidity under 35 U.S.C. §§ 102(f) and 112. Counterclaimants have no reasonable basis for precluding such testimony.

C. *Motion to Preclude Ferring from Offering Evidence or Testimony related to Dr. Fein's Response to the Notice of Opposition in the EPO.*

1. Background

Ferring initiated an opposition proceeding before the EPO after Dr. Fein was awarded a European patent for some of his other "work"[2]—work directed to a specific "metered dose spray device" used for delivery of an intranasal dosage form. In opposing the issuance of that patent, Ferring argued to the EPO that the claims of Dr. Fein's European "metered dose spray" patent were invalid in light of prior art references, including the '203 patent at issue here. According to Counterclaimants, Ferring argued that the prior art, including Dr. Fein's '203 patent "enabled," or was obvious, and so negated the novelty or inventive step of Dr. Fein's intranasal dosage form European patent claim that Ferring was opposing.

Counterclaimants assert that "enabled" under European patent law, has a different meaning than "enabled" under United States patent laws. According to Counterclaimants, under European law, whether something is "enabled" by prior art reference asks whether the prior art was obvious or negated the inventive step.

[2] Despite Counterclaimants assertion that Dr. Fein was granted the patent—Eur '821—for his "inventive work," the EPO has revoked Eur '821. (*See* Cox Decl. Ex. C at 2, August 30, 2019 entry ("Despatch of communication that the patent will be revoked").)

Under United States law by contrast, enablement is the requirement that a patent set forth the "manner and process of making and using [the invention] … as to enable any person skilled in the art to which it pertains … to make and use the same." § 112, ¶ 1.

Counterclaimants allege that Ferring now takes "enabled" out of its European context in alleging that that Dr. Fein has admitted that the '203 patent claims are not enabled under U.S. patent laws. To Counterclaimants, this is simply a matter of the particular word, "enabled," having two different meanings under the U.S. and European patent laws.

2. Counterclaimants' motion to preclude Ferring from offering evidence or argument related to Dr. Fein's response to the Notice of Opposition in the EPO Proceedings is DENIED

Counterclaimants have not cited a single citation to any European law or regulation tending to show that "enabled" has "two entirely different meanings under the U.S. and European patent laws." (Dkt. No. 652 at 1.)

By contrast, Ferring intends to show, through the testimony of its expert Dr. Polz, that under EPO case law and EPO examination guidelines, a prior art reference must have an enabling disclosure "such that the skilled person can reproduce the subject-matter using common general knowledge." (Dkt. No. 632 at ¶¶ 7-13 (*quoting* DX-52-0001).) This "enablement" requirement under European law for a prior art reference would be the same as under U.S. law, both being directed to whether the disclosure is sufficient for the skilled person to practice the technical teaching which is the subject of the prior art document. Dr. Polz so explained at his deposition. (*See* Cox Decl. Ex. B. at, *e.g.*, 23:9-19, 36:12-21, 37:11-38:16.)

This is relevant because in their argument before the EPO, Serenity stated that:

> It is noteworthy that the teaching of [the '203 patent] with respect to the Table in Col. 17 is not enabled, i.e. there is [sic] no examples demonstrating that any of the suggested dose ranges are effective to establish a steady plasma/serum desmopressin concentration in the range of from about .1 picograms of desmopressin per mL plasma/serum to about 10.0 picogram desmopressin per mL plasma/serum in a patient, let alone provide therapeutic efficacy for the conditions indicated above (e.g., inducing an antidiuretic effect for less than about 6 hours, and which lower the risk of hyponatremia).

(DX-38-0044 at ¶ 11.14 (emphasis in original).) Ferring intends to show that before the EPO, Serenity argued that the disclosure of the '203 patent does not provide sufficient disclosure for the claimed limitations in the '203 patent, namely that there are no examples of the suggested dose ranges to achieve certain plasma concentrations much less provide therapeutic efficacy.

If so, Serenity's argument that the '203 patent is not enabled before the EPO, would be relevant as an admission against interest. *See, e.g.*, *Funai Elec. Co. v. Orion Elec. Co.*, No. 01-cv-3501 (AGS)(JCF), 2002 WL 1808419, at *2 (S.D.N.Y. Aug. 7, 2002) ("Actions and statements against interest of the owner of a patent or inventor may be considered by a court

when construing the scope of a patent and are relevant to the issues of infringement and validity" (internal quotation admitted).).

Counterclaimants' motion *in limine* seems far better suited for a cross-examination of Dr. Polz at the bench trial.

Ferring's *In Limine* Challenges

Ferring has submitted a motion *in limine* to preclude testimony of Teresa Stanek Rea, the former Acting Under Secretary of Commerce for Intellectual Property and former Acting Director of the PTO on the grounds that her proposed testimony "(1) parrots the rules of PTO practice and procedure and the law, (2) opines on matters not relevant to any claim or defense to be presented at trial, (3) opines on the intent or state of mind of Dr. Seymour Fein, and/or (4) opines on issues admittedly beyond her expertise." (Dkt. No. 643 at 1.)

However, because the Court is granting Counterclaimants' motion for judgment on the pleading dismissing Ferring's inequitable conduct affirmative defense, Ferring's motion is moot. (*See* Dkt. No. 647 at 1 ("Ferring's motion will be moot if Counterclaimants' pending Rule 12(c) Motion to preclude Ferring's inequitable conduct and 102(f) affirmative defenses is granted, because Ms. Rea would no longer be called as a trial witness.").)

CONCLUSION

This constitutes the decision and order of the court. It is a written opinion. The Clerk is directed to remove the following motions from the court's list of open motions: Docket ## 642, 646, 649, and 651.

Dated: March 11, 2020

Chief Judge

BY ECF TO ALL COUNSEL